

REMARKS

Reconsideration of the application is requested in view of the above amendments and the following remarks. A sequence listing has been provided and the specification has been amended accordingly. No new matter has been added with the addition of the Sequence Listing and amendments to the specification. Claims 28-55 have been amended. Support for the amendment to claims 25 and 54 can be found at page 21, lines 21-30 of the application. No additional matter that would require support in the specification has been added to the claims by virtue of the amendments included herein.

Objections to the Specification

The specification was objected to for failing to include a sequence listing for nucleotide sequences over 10 nucleotides in length or peptides over 4 amino acids in length. Applicant has provided both a paper copy and a computer readable copy of the Sequence Listing. The paper copy and the computer readable copy are the same. Applicant respectfully requests the withdrawal of this objection.

Claim Rejections Under 35 U.S.C. § 112

Claims 28-55 were rejected under 35 U.S.C. § 112, ¶ 2, as indefinite. Applicant respectfully traverses this rejection.

In order to advance prosecution of the case, the claims have been amended to remove phrases including characterizing language. Any such phrases have been amended to include the preferred transitions, "wherein" and comprising." Optional limitations and limitations including the term "such as" have been removed from the claims. In addition, Markush groups have been added to the claims where appropriate.

Claim 32 was rejected because the Examiner believed the way the peptide or synthetic binder is identified does not limit the peptide or binder itself. Applicant respectfully traverses this rejection. In order to advance the prosecution, however, the relevant limitation has been deleted. Applicants respectfully request withdrawal of the rejection of claim 32.

Claims 33-36 were rejected for failing to set forth affirmative steps required by the claimed method of each claim. Applicant respectfully traverses this rejection. Claims 33-36 each require the use of certain reagents. In other words, claims 33-36 involve an affirmative step, i.e. the use of certain reagents. Applicant respectfully requests withdrawal of this rejection.

Claim 36 was further rejected for containing inappropriate claim terminology. Applicant respectfully traverses this rejection. Applicant respectfully contends that in view of the amendment the rejection of claim 36 has been rendered moot.

Claim 41 was rejected because it claimed the use of compounds based upon the marks such compounds are sold under. Applicant respectfully traverses this rejection. In order to advance prosecution, however, compounds claimed under their respective trademarks have been removed from the claim. Accordingly, Applicant respectfully contends this rejection has been rendered moot.

Claim 46 was rejected for lacking an antecedent basis. Applicant respectfully traverses this rejection. In view of the amendment to claim 46, however, the Applicant respectfully contends this rejection has been rendered moot.

Claim 48 was rejected for failing to indicate what element was being described in the body of the claim. In view of the amendment to claim 48, however, the Applicant respectfully contends this rejection has been rendered moot.

Claims 50-52 were rejected because they are product claims but depended from a method claim. Applicant respectfully traverses this rejection. In view of the amendment to claims 50-52, however, the Applicant respectfully contends this rejection has been rendered moot.

Claim 53 was rejected for failing to set forth affirmative steps required by the claimed method. Claim 53 was also rejected for lacking guidance as to the scope of the claim. Applicant respectfully traverses this rejection. One having ordinary skill in the relevant art recognizes that certain substances have a biological impact for living organisms. Moreover, such a person would also recognize that living organisms require certain substances in order to sustain life. This would include substances that a living organism might need to fight disease or otherwise inhibit maladies. In addition, one of ordinary skill in the art could readily determine what substances a living organism requires. Accordingly, Applicant respectfully requests the withdrawal of this rejection.

Claim 54 was rejected for referring to claim 48. Applicant respectfully traverses this rejection. In view of the amendment to claim 48, however, the Applicant respectfully contends this rejection has been rendered moot.

Claim Rejections Under 35 U.S.C. §101

Claim 53 was rejected under 35 U.S.C. §101 as being an improper process claim. Applicant respectfully traverses this rejection. Claim 53 expressly requires the affirmative step of determining the concentration of a biologically relevant substance. Accordingly, Applicant respectfully contends claim 53 satisfies the requirements of 35 U.S.C. §101.

Claim Rejections Under 35 U.S.C. § 102

Jolley et al.

Claims 28, 29, 34, 39-47, 49 and 53 were rejected under 35 U.S.C. § 102 as anticipated by Jolley et al. (U.S. Pat. No. 5,976,820).

Claim 28 is limited to the analysis of analytes that are not antibodies. This method can be used to analyze analytes of all different kinds and in many forms, such as whole blood, using a single reagent.

Jolley teaches a high specificity assay method in which a flourophore-conjugated antigen dissolved freely in reaction reacts with analyte antibodies to form an immune complex. (Col. 2, ll. 52-54). The levels of this immune complex can be detected through the change in fluorescence polarization. (Col. 2, ll. 54-56). Jolley only teaches the detection of antibodies, no other forms of analytes can be detected under the method. Accordingly, Applicant respectfully contends Jolley fails to anticipate claim 28.

Claims 29, 34, 39-47, 49 and 53 depend from claim 28, an allowable base claim. For at least this reason, Applicant respectfully contends Jolley fails to anticipate these claims as well.

Nakayama et al.

Claims 28-55 were rejected under 35 U.S.C. § 102 as anticipated by Nakayama et al. (WO99/13332). As recognized by the Examiner, U.S. Pat. No. 6,432,632 is a proper English equivalent of this reference. All references to Nakayama are made to U.S. Pat. No. 6,432,632.

Under claim 28, when the reagent used comprises a binding pair including an aptamer, a peptide or peptidic synthetic binder complexed with a fluorescent moiety to form a fluorescent complex having a changed size, the aptamer, peptide, or synthetic peptidic binder must have a molecular weight of 5,000 or less. The method of claim 28 is directed to low molecular weight binders, whereby larger changes in fluorescence polarization can be observed so that lower molecular weight analytes may be assayed. (See application page 21, lines 21-34).

Nakayama is directed to a method for assaying high molecular weight substances (Col. 1, ll. 61-66; col. 6, ll. 51-60; col. 7, ll. 6-13). Nakamaya teaches an assay system in which a change in molecular weight that occurs when a fluorescently-labeled protein binds to the analyte is measured as a change over time in the molecular orientation. (Col. 4, ll. 22-25). The degree of polarization of fluorescence emitted from the fluorescent-labeled protein bound to the analyte is proportional to the size of the molecule. (Col. 5, ll. 36-39). In other words, the assay relies upon a difference in size between the bound and unbound fluorescent-labeled proteins. Nakamaya is directed to the analysis of high molecular weight analytes, wherein the protein that is fluorescently labeled must have a sufficiently large molecular weight in order to produce a sufficiently noticeable change in fluorescence-polarization. Specifically, Nakayama teaches the use of labeled antibodies and FAB and FAB₂ fragments of such antibodies. All the binders taught in the Examples of Nakayama have a molecular weight of 50,000 or more. Nakayama does not teach the use of fluorescently labeled binding pairs wherein the aptamer, peptide binder, or synthetic binder has a molecular weight of 5,000 or less. As a result, the method taught by Nakayama cannot be used to analyze analytes having lower molecular weights. For at least this reason, Applicant respectfully contends Nakayama fails to anticipate claim 28.

Nakayama mentions that fluorescent labeled receptors or inhibitors may be used. Applicant respectfully contends Nakayama fails to enable one of ordinary skill in the art to perform the Nakayama method using fluorescent labeled receptors or inhibitors. Nakayama merely mentions the possibility of using fluorescent labeled receptors or inhibitors without teaching how they may be prepared and/or used. *See in re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). For at least this reason as well, Applicant respectfully contends Nakayama fails to anticipate claim 28.

Claims 29-53 depend from claim 28, an allowable base claim. For at least this reason, Applicant respectfully contends Nakayama fails to anticipate these claims as well.

Claim 54 involves the same limitations with respect to the binding pair as claim 28. Accordingly, for the same reasons that Nakayama fails to anticipate claims 28, Nakayama fails to anticipate claim 54.

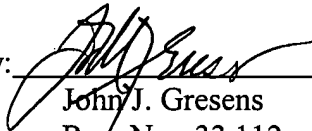
Claim 55 depends from claim 54, an allowable base claim. For at least this reason, Applicant respectfully contends Nakayama fails to anticipate this claim as well.

In view of the above, Applicant respectfully requests reconsideration of the application in the form of a Notice of Allowance.

Respectfully submitted,

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